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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/882,431	06/25/97	ULRICH R	003/037/SAP

HM12/0719

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EXAMINER	
ALLEN, M	
ART UNIT	**PAPER NUMBER**
1645	12

DATE MAILED: 07/19/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/882,431	Applicant(s) Ulrich et al.
	Examiner Marianne P. Allen	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Mar 24, 1999*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-70 and 100-109* is/are pending in the application.

Of the above, claim(s) *see Office action* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43, 44, 47-49, 53, 56-58, 62, and* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-70 and 100-109* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *8*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 2-3, 7-11, 15-17, 19-20, 24-28, 32-36, 40-42, 45-46, 50-52, 54-55, 59-61, 63-64, 68-70, and 100-109 remain withdrawn from further consideration by the examiner as being drawn to a non-elected invention.

Applicant is again advised that generic claims 1, 18, 43-44, 53, and 62 have been examined on the merits only to the degree that they reflect the elected invention Staphylococcal enterotoxin B.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 3/24/99 have been fully considered but they are not persuasive.

The rejection of claims 1, 18, 43-44, 53, and 62 under 35 U.S.C. 102(a) as being anticipated by Bavari et al. (Vaccines 96) is withdrawn in view of the 1.132 declaration removing this reference as prior art.

The rejection of claims 1, 18, 43-44, 53, and 62 under 35 U.S.C. 102(b) as being anticipated by Hayball et al. (International Immunology, 1994) is withdrawn in view of applicant's amendment to the claims. However, in view of the new matter rejection, this art could be reapplied once the new matter rejection is resolved.

The substitute paper copy of the sequence listing is noted; however, no substitute CRF appears to have been submitted and it is unclear if applicant is implying that the previous CRF and the present paper copy are identical and contain no new matter. Clarification is requested and failure to do so this will result in an assumption of non-compliance with the sequence rules. Applicant should clearly identify the paper copy and/or CRF that they are referring to (by submission date or some other identifying feature).

Applicant is again advised that the examiner has not made an exhaustive comparison of sequences for new changes introduced and/or additional inconsistencies.

The disclosure remains objected to because of the following informalities: The specification fails to reference or identify the SEQ ID NOS. disclosed in the sequence listing in the brief description of the drawings (see for example description of Figure 3 on page 10).

Appropriate correction is required.

The specification remains objected to as failing to provide proper antecedent basis for the claimed subject matter. Correction of the following is required: The recombinant DNA constructs pETA489270C, pETB2360210, and pETB899445P claimed in claims 37-39 do not appear to be disclosed in the specification. Note that this is not a new matter rejection as the originally filed claims recite these constructs. The specification must be amended to refer to the claimed subject

matter. Applicant is again directed to 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The specification at pages 21-22 and 32 do not name these constructs.

Claims 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43-44, 47-49, 53, 56-58, 62, and 65-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to refer to multiple subsets of T cells with basis given as Example 8. This example is with reference to particular constructs of SEA not SEB (the particular species under examination) and cannot be viewed as basis to support a generic claim to any superantigen toxin encompassed by the claims. It is unclear if any of the exemplified SEB mutants exhibit this property. Applicant is requested to point to particular basis in the specification by page and line number for this new claim limitation.

In addition, the enablement of claims 37-39 requires availability of the named DNA constructs and a deposit should have been made in accordance with MPEP 2402 as set forth in the prior Office action. In order to certify that the deposit meets the criteria set forth in MPEP 2402, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number. Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is

provided that the deposited materials will be made irrevocably available with no restrictions upon issuance of a patent. No such statement has been provided nor does the specification appear to reflect the deposit information (ATCC numbers, date of deposit, address of the depository, etc.). Applicant's argument concerning insertion of nucleic acids into well known and readily available vectors is not persuasive with regard to enablement as the specification does not make clear which sequences were inserted into which vectors to produce the named constructs. The only way to enable claims 37-39 (once the new matter rejection set forth above is resolved) is to perfect the deposits.

As set forth in the prior Office action claims 44, 47-49, 62, and 65-67 are directed to host cells and methods of producing altered superantigen toxins using the host cells. Because the claims do not indicate that these are isolated host cells the claims can be construed to encompass transgenic animals and methods of producing the toxins in transgenic animals. Such animals and methods do not appear to be disclosed nor enabled by the specification. It would not have been routine to produce toxins in this manner at the time of the invention. Applicant has not responded to this portion of the rejection.

Claims 4-6, 12-14, 18, 21-23, 43-44, 53, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These rejections are maintained for reasons of record and have not been addressed by applicant.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
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